**UNITED STATES DISTRICT COURT**
**DISTRICT OF VERMONT**

Marion Johnson, individually and on behalf of all others similarly situated;

Plaintiff,

v.

Ethex Corporation and
K-V Pharmaceutical Company,

Defendants.

Case No. 2:08-CV-213

**FIRST AMENDED COMPLAINT – CLASS ACTION**

Representative Plaintiff, Marion Johnson, on behalf of herself and all others similarly situated, alleges as follows:

## JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the parties are citizens of different States and the matter in controversy exceeds the jurisdictional amount exclusive of interest and costs.

2. Venue is proper under 28 U.S.C. §§ 1391(a) because the Representative Plaintiff resides in this district, and because she ingested Ethex Morphine Sulfate ER Tablets in this district.

## PARTIES

3. Representative Plaintiff, Marion Johnson, is a citizen of the State of Vermont, and resides in Rutland, Vermont.

4. Defendant, Ethex Corporation ("Ethex"), is a Missouri Corporation with its principal place of business in St. Louis, Missouri.

5. Defendant, K-V Pharmaceutical Company ("KV"), is a Delaware Corporation with its principal place of business in St. Louis, Missouri.

**FACTS**

6. Defendant KV manufactures Morphine Sulfate Extended Release ("ER") Tablets. Defendant Ethex, a wholly owned subsidiary of KV, markets, promotes, and distributes KV's Morphine Sulfate ER Tablets throughout the United States.

7. On June 9, 2008, Ethex voluntary recalled a single lot (Lot. No. 91762) of Morphine Sulfate ER 60 mg tablets (the "June 9 Recall").

8. According to a press release issued by Ethex, the June 9 Recall followed the report of an oversize tablet. The press release warned that oversize tablets may contain as much as twice the labeled level of active morphine sulfate.

9. The press release stated that Ethex distributed the Morphine Sulfate ER 60 mg tablets subject to the June 9 Recall under the "Ethex" label between April 16 and April 27 2008.

10. On June 13, 2008, Ethex expanded the recall to include additional morphine sulfate tablets distributed between June 2006 and May 2008 – a nearly two year period (the "June 13 Recall"). The June 13 Recall applied to Morphine Sulfate ER 30 mg Tablet Lots 75090, 77846, 77847, 80048, 83320, 89661, 89665, 90252 through 90258, and 93284, and Morphine Sulfate ER 60 mg Tablet Lots 91762 (previously reported) 75091, 75092, 77848 through 77851, 82517, 82518, 83333, 83817, 83862, 84111, 84112, 84315, 84900, 85326, 85335, 85807, 86270 through 86276, 87723, 87939, 88007, 89083, 89668, 89669, 89821, 90260 through 90272, and 91763 through 91765. (The Morphine Sulfate ER tablets that were subject to the June 9 Recall and the July 13 Recall are hereinafter collectively referred to as "the Recalled Morphine Sulfate.")

11. Morphine sulfate, a highly potent opiate analgesic, is potentially fatal if overdosed. Side effects of a non-fatal morphine sulfate overdose can include respiratory depression (difficulty or lack of breathing), low blood pressure (hypotension), and apnea.

12. Representative Plaintiff suffers from painful medical conditions.

13. Representative Plaintiff treats the pain from her underlying conditions with, among other drugs, morphine sulfate. She has a prescription for morphine sulfate ER 60 mg tablets, and takes two tablets per day.

14. On May 6, 2008, Representative Plaintiff filled her prescription for morphine sulfate at the local Walgreens store in Rutland, Vermont. That evening, she took the first pill from the bottle she had obtained earlier in the day.

15. On or about May 6, 2008, Representative Plaintiff and her longtime companion, began driving on a trip to Florida. During the drive south, which took several days, Representative Plaintiff began experiencing severe symptoms. These symptoms included: respiratory distress, severe headaches, slurred speech, disorientation/confusion, blurry vision, nausea, vomiting, seizures, and dizziness.

16. By the time Representative Plaintiff and her companion arrived in Kentucky, Representative Plaintiff was unable to continue to Florida. Representative Plaintiff ended up staying in motel rooms in Florence, Kentucky for several days. On May 31, 2008, Representative Plaintiff went to the emergency room at St. Luke's Hospital in Florence, Kentucky. She was treated for breathing problems and released.

17. Representative Plaintiff eventually returned to Vermont where she learned that the morphine sulfate tablets she had been taking for a month had been recalled as part of the Recalled Morphine Sulfate.

## ALLEGATIONS

18. Defendants negligently designed, manufactured, marketed, promoted, sold, and/or distributed the Recalled Morphine Sulfate, which was unreasonably dangerous in normal use because it had potentially twice the approved level of active ingredient.

19. Defendants failed to adequately warn Recalled Morphine Sulfate users of the drug's unreasonably dangerous characteristics.

20. Defendants owed a legal duty to Representative Plaintiff and Plaintiff Class Members to manufacture and sell the Recalled Morphine Sulfate without hidden and concealed defects.

21. Defendants breached their duty and proximately caused Representative Plaintiff's and Plaintiff Class Members' damages.

22. Defendants knew, or in the exercise of reasonable care should have known, that the Recalled Morphine Sulfate was defective and that Representative Plaintiff and Plaintiff Class Members might be reasonably expected to use the drug and be affected by its defective condition.

23. The Recalled Morphine Sulfate's defective condition is a direct and proximate cause of Representative Plaintiff's and Plaintiff Class Members' injuries.

## CLASS ACTION ALLEGATIONS

24. Representative Plaintiff brings this action on behalf of herself and all others similarly situated, as a member of a proposed nationwide plaintiff class (the "Class") of all persons in the United States who purchased and/or ingested the Recalled Morphine Sulfate.

25. This action is brought and may properly be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a)(1)-(4), 23(b)(2), and 23(b)(3). This action satisfies

these provisions' numerosity, commonality, typicality, adequacy, predominance, and superiority requirements.

26. The Class is so numerous that the individual joinder of all members is impracticable. While the Class's exact number and the identity of class members is currently unknown and can only be ascertained through appropriate discovery, Representative Plaintiff is informed and believes that the Class includes thousands of individuals.

27. Common legal and factual questions exist that predominate over any questions affecting only individual Class members. These common questions, which do not vary from Class member to Class member, and which may be determined without reference to any Class member's individual circumstances, include, but are not limited to:

a. Whether there are design and/or manufacturing defects in the Recalled Morphine Sulfate;

b. Whether Defendants designed, manufactured, and/or marketed a defective product;

c. Whether Defendants' conduct in designing, manufacturing, and marketing the Recalled Morphine Sulfate fell below the duty of care Defendants owed Representative Plaintiff and the other Class members;

d. Whether Defendants are liable for selling a dangerously defective product;

e. Whether Defendants failed to adequately warn or notify patient recipients of the adverse health hazards the Recalled Morphine Sulfate caused;

f. Whether Defendants breached express or implied warranties;

g. Whether Defendants' conduct constitutes negligence;

h. Whether Defendants violated consumer protection statutes;

i. Whether Class members are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

j. Whether the Class is entitled to compensatory damages, and if so, the stature and amount of such damages; and

k. Whether Defendants are liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish Defendants for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages.

28. Representative Plaintiff's claims are typical of the Class members' claims. Defendants' common course of conduct caused Representative Plaintiff and all Class members the same damages. In particular, Defendants' conduct caused each Class member's physical and emotional injuries and economic losses. Likewise, Representative Plaintiff and other Class members must prove the same facts in order to establish the same claims.

29. Representative Plaintiff is an adequate Class representative because she is a Class member and her interests do not conflict with Class interests. Representative Plaintiff retained counsel competent and experienced in products liability and mass torts class actions, and together Representative Plaintiff and counsel intend to prosecute this action vigorously for the Class's benefit. Representative Plaintiff and her counsel will fairly and adequately protect Class interests.

30. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because individual litigation of each Class member's claim is impracticable. Even if each Class member could afford individual litigation, the court system

could not. It would be unduly burdensome if thousands of individual cases proceed. Likewise, individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, as well as the risk of an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation further increases the expense and delay to all parties and the courts because it requires individual resolution of common legal and factual questions. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

31. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Federal Rules of Civil Procedure 23(b)(l) and/or 23(b)(2) because:

a. Separate actions would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Defendants.

b. Separate actions would create the risk of adjudications that would, as a practical matter, be dispositive of other non-party Class member's interests, thereby substantially impairing or impeding non-party Class members' ability to protect their interests.

c. Defendants have acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
### (Strict Products Liability)

32. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

33. At all relevant times hereto, Defendants were engaged in the business of researching, designing, manufacturing, assembling, promoting, testing, marketing, selling, and distributing the Recalled Morphine Sulfate that Representative Plaintiff and the Class ingested.

34. The Recalled Morphine Sulfate was expected to and did reach the Representative Plaintiff and the Class without substantial change in its condition as manufactured and sold by Defendants. In light of the defects described herein, at the time the Recalled Morphine Sulfate reached the Representative Plaintiff and the Class, it was in a condition not contemplated by any reasonable person among expected morphine sulfate users, and was unreasonably dangerous to expected morphine sulfate users when used in reasonably expected ways of handling or consumption.

35. The Recalled Morphine Sulfate that Defendants designed, manufactured, assembled, marketed, distributed, and/or sold to Representative Plaintiff and the Class was defective in design or formulation and was therefore unreasonably dangerous to any morphine sulfate user. Representative Plaintiff and the Class were, and are, among those that Defendants should reasonably have foreseen as being subject to the harm caused by the Recalled Morphine Sulfate's defective condition.

36. Representative Plaintiff and the Class used the Recalled Morphine Sulfate in the manner in which the Recalled Morphine Sulfate was intended to be used. This has resulted in severe and life threatening injuries to Representative Plaintiff and the Class.

37. Representative Plaintiff and the Class were not aware of, and could not in the exercise of reasonable care have discovered, the Recalled Morphine Sulfate's defective nature, nor could they have known that Defendants designed and manufactured the Recalled Morphine Sulfate in a manner that would increase the risk of bodily injury,

38. As a direct and proximate result of Defendants' design, manufacture, marketing, distribution, and sale of the Recalled Morphine Sulfate, Representative Plaintiff and the Class have sustained and will continue to sustain severe physical injuries, severe emotional distress, and economic losses and consequential damages, and are therefore entitled to compensatory relief according to proof, and entitled to a declaratory judgment that Defendants are liable to them for breach of their duty to Representative Plaintiff and the Class and for Defendants' failure to provide a safe and effective drug.

39. Defendants' Recalled Morphine Sulfate constitutes a product dangerous for its reasonably intended use, due to defective design, manufacture, assembly, and marketing. Defendants are therefore liable to Representative Plaintiff and the Class in an amount according to proof.

**SECOND CLAIM FOR RELIEF**
**(Breach of Implied Warranty)**

40. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

41. Defendants impliedly warranted that their Recalled Morphine Sulfate, which Defendants designed, manufactured, assembled, promoted and sold to Representative Plaintiff and the Class, was merchantable and fit and safe for ordinary use. Defendants further impliedly warranted that their Recalled Morphine Sulfate was fit for the particular purpose for which the product was to be used.

42. Defendants' Recalled Morphine Sulfate was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which it was sold, and subjected Representative Plaintiff and the Class to severe and permanent injuries and death. Therefore, Defendants breached the implied warranties of merchantability and fitness for a particular purpose when its Recalled Morphine Sulfate was sold to Representative Plaintiff and the Class, in that the Recalled Morphine Sulfate was defective and failed to function as represented and intended.

43. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness for a particular purpose, Representative Plaintiff and the Class have sustained severe physical injuries, severe emotional distress, and economic losses, and are therefore entitled to compensatory damages and equitable relief according to proof.

**THIRD CLAIM FOR RELIEF**
**(Negligence)**

44. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs, as if set forth verbatim.

45. Defendants had a duty to Representative Plaintiff and the Class to design and manufacture a safe product. Defendants breached their duty of reasonable care to Representative Plaintiff and the Class by incorporating a defect into the design and manufacture of the Recalled Morphine Sulfate, thereby causing Representative Plaintiff and the Class injury.

46. Defendants breached their duty of reasonable care to Representative Plaintiff and the Class by manufacturing and assembling the Recalled Morphine Sulfate in such a manner that it exposed Representative Plaintiff and the Class to life-threatening physical trauma and pain.

47. Defendants breached their duty of reasonable care to Representative Plaintiff and the Class by failing to exercise due care under the circumstances.

48. As a direct and proximate result of the Defendants' carelessness and negligence, Representative Plaintiff and the Class have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages. As a result, Representative Plaintiff and the Class are entitled to compensatory damages and equitable and declaratory relief according to proof. Defendants' egregious misconduct alleged above also warrants the imposition of punitive damages against Defendants.

**FOURTH CLAIM FOR RELIEF**
**(Violation of Vermont Consumer Protection Statutes)**

49. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

50. Representative Plaintiff and the Class bring this cause of action pursuant to the Vermont Consumer Fraud Act (the "Act"), 9 V.S.A. 2461(b), in that Plaintiff and the Class purchased the Recalled Morphine Sulfate for their personal use and thereafter suffered damages.

51. Defendants were at all times relevant to this Complaint, sellers within the meaning of 9 V.S.A. § 2451a(c).

52. Representative Plaintiff and the members of the Class were at all times relevant to this Complaint, "consumers" within the meaning of 9 V.S.A. § 2451(a)(a).

53. Defendants falsely and/or fraudulently represented that the Recalled Morphine Sulfate contained the amount of morphine sulfate listed and/or advertised.

54. Defendants omitted the information that the Recalled Morphine Sulfate did not contain the amount of morphine sulfate listed and/or advertised.

55. Defendants engaged in unfair methods of competition in commerce, or unfair or deceptive acts or practices in commerce, in violation of 9 V.S.A. § 2543(a).

56. Representative Plaintiff and the Class are consumers who contracted for goods in reliance upon Defendants' conduct which was violative of 9 V.S.A. § 2543(a).

57. The representations and/or omissions regarding the amount of morphine sulfate contained in the Recalled Morphine Sulfate were likely to mislead consumers.

58. Representative Plaintiff and the Class reasonably interpreted Defendants' statements and/or omissions to mean that the Recalled Morphine Sulfate contained the amount of morphine sulfate listed and/or advertised.

59. The misleading representations and/or omissions were material in that they affected the Representative Plaintiff and the Class' purchasing decisions.

60. Had Defendants not engaged in the deceptive conduct described above, Representative Plaintiff and the Class would not have purchased and/or paid for the Recalled Morphine Sulfate and would not have incurred related medical costs.

61. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Representative Plaintiff and the Class, constituted unfair and deceptive acts and practices in violation of the Vermont Consumer Fraud Act, 9 V.S.A. 2453(a).

62. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Representative Plaintiff and the Class for the Recalled Morphine Sulfate that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

63. Representative Plaintiff and the Class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Recalled

Morphine Sulfate. Each aspect of Defendants' conduct combined to artificially create sales of the Recalled Morphine Sulfate.

64. The medical community relied upon Defendants' misrepresentations and omissions in determining which morphine sulfate to utilize.

65. By reason of the unlawful acts engaged in by Defendants, Representative Plaintiff and the Class have suffered ascertainable loss and damages.

66. Representative Plaintiff and the Class are entitled to the amount of their damages, or the consideration or the value of the consideration given by them, reasonable attorney's fees, and exemplary damages pursuant to 9 V.S.A. § 2461(b).

**FIFTH CLAIM FOR RELIEF**
**(Breach of Express Warranties)**

67. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

68. Defendants expressly warranted to Representative Plaintiff and the Class by and through Defendants and/or their authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the Recalled Morphine Sulfate was safe, effective, fit and proper for its intended use.

69. In ingesting the Recalled Morphine Sulfate, Representative Plaintiff and the Class relied on Defendants' skill, judgment, representations, and express warranties. These warranties and representations were false because the Recalled Morphine Sulfate was not safe and was unfit for the uses for which it was intended.

70. Through its sale of the Recalled Morphine Sulfate, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

71. Any disclaimers of express warranties are ineffectual as they were not provided to

Representative Plaintiff and the Class or otherwise made known to Representative Plaintiff and the Class. In addition, any such disclaimers are unconscionable.

72. As a direct and proximate result of Defendants' breach of express warranty, Representative Plaintiff and the Class have sustained economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Representative Plaintiff and the Class in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages in unconscionable. Defendants are liable to Representative Plaintiff and the Class for all damages to which Representative Plaintiff and the Class are entitled by law.

**SIXTH CLAIM FOR RELIEF**
**(Unjust Enrichment)**

73. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

74. As the intended and expected result of its conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Recalled Morphine Sulfate.

75. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Representative Plaintiff and the Class, with full knowledge and awareness that, as a result of Defendants' wrongdoing, Representative Plaintiff and the Class were not receiving a product of the quality, nature or fitness that Defendants have represented or that Representative Plaintiff and the Class, as reasonable consumers, expected.

76. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Representative Plaintiff and the Class, who are entitled to

in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

**SEVENTH CLAIM FOR RELIEF**
**Negligent Misrepresentation**

77. Representative Plaintiff, individually and on behalf of the Class, re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

78. At the time Defendants manufactured, designed, marketed, sold, and distributed the Recalled Morphine Sulfate for use by Representative Plaintiff and the Class, Defendants knew of (or should have known of) the Recalled Morphine Sulfate's intended use and the serious risks and dangers associated with such use.

79. Defendants owed a duty to treating physicians and ultimate end users of the Recalled Morphine Sulfate, including Representative Plaintiff and the Class, to accurately and truthfully represent the risks of the Recalled Morphine Sulfate. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Recalled Morphine Sulfate, effects of which Defendants knew or in the exercise of diligence should have known, to the treating physicians and ultimate end users, including Representative Plaintiff and the Class.

80. As a direct and proximate result of Defendants' wrongful conduct, Representative Plaintiff and the Class have sustained, and will continue to sustain, severe and physical injuries, and/or death, severe emotional distress, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Representative Plaintiff and the Class for all general, special and equitable relief to which they are entitled by law.

## PRAYER FOR RELIEF

WHEREFORE, Representative Plaintiff prays for judgment against Defendants as follows:

a. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Representative Plaintiff and her counsel to represent the Class;

b. For the equitable relief requested;

c. For compensatory damages according to proof;

d. For a declaratory judgment that Defendants are liable to them for breach of their duty to Representative Plaintiff and the Class and for Defendants' failure to provide a safe and effective drug;

e. For punitive or exemplary damages against Defendants, consistent with the degree of Defendants' reprehensibility and the resulting harm or potential harm to Representative Plaintiff and the Class, and in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

f. For all applicable statutory damages under the consumer protection legislation of Vermont;

g. For a restitution and disgorgement of profits;

h. For an award of attorneys' fees and costs;

i. For prejudgment interest and the costs of suit; and

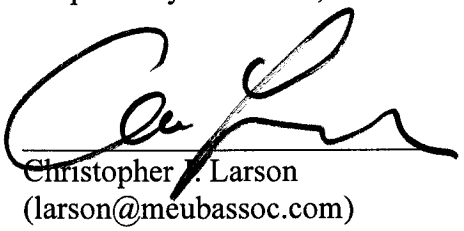
j. For such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Representative Plaintiff hereby demands a trial by jury.

Dated at Rutland, Vermont, this 6th day of November 2008.

Respectfully submitted,



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